UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,875	06/27/2005	Chris Armstrong	002.00240	6263

35876 7590 04/23/2007

ROGALSKY & WEYAND, LLP
P.O. BOX 1927
WILLIAMSVILLE, NY 14231-1927

EXAMINER	
BRADLEY, CHRISTINA	
ART UNIT	**PAPER NUMBER**
1654	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,875	ARMSTRONG ET AL.	
	Examiner	Art Unit	
	Christina Marchetti Bradley	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *17-23* is/are withdrawn from consideration.

5)☐ Claim(s) *10* is/are allowed.

6)☐ Claim(s) *1-9,12-16,24 and 25* is/are rejected.

7)☐ Claim(s) *11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/16/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
✓6) ☒ Other: *Notice to Comply*.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-16, 24 and 25 in the reply filed on 10/13/2006 is acknowledged.

Sequence Compliance

2. This application is objected to because the amino acid sequences on pages 5, 7, 11-13, 18, 19, 21, 25, 30 and 31 and in Figure 1 are not associated with a sequence identifier (a SEQ ID NO). All sequences longer than four amino acids referenced in the specification must include a SEQ ID NO and must be included in the Sequence Listing. See MPEP § 2421-2422 and Notice to Comply.

Claim Objections

3. Claims 1-9, 24 and 25 are objected to because of the following informalities: "wherein said specific binding partner in not" in claim 1 should be "wherein said specific binding partner is not". Appropriate correction is required.

4. Claim 11 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 10. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1- 9, 12-16, 24 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

6. Claims 1-6, 8, 9, 24 and 25 are drawn to a kit of parts comprising two or more protein kinase substrate polypeptides. Claims 8, 9, 24 and 25 also specify that the kit comprise a binding partner for the substrate peptides that is responsive to the phosphorylation state of the polypeptides. Claims 12-16 are drawn to polypeptide comprising SEQ ID NO: 6 with up to 5 residues substituted and a consensus sequence. The specification discloses the complete structure of the following polypeptides comprising SEQ ID NO: 6: RARTLSFAEPG, KKLNRTLSFAEPG and RRRLSFAEPG (recited in the legend for figure 2). The claimed genus is much broader than this well-defined subgenus. The minimal structural requirements for the genus are that the polypeptides comprise a phosphorylatable portion (i.e. a serine, threonine or tyrosine) and a specificity conferring portion that is different for each polypeptide in the kit. An infinite number of polypeptides could satisfy these minimal requirements. Despite this breadth, the specification does not disclose the complete or partial structure or chemical/physical

properties of any additional peptides, or guidance on how to obtain specific polypeptides suitable for the kit. The consensus sequences recited in claim 15 are extremely broad. SEQ ID NOs: 2, 5, 8 and 9 have 4, 4, 4 and 5 undefined positions, respectively, with the only defined position in SEQ ID NO: 2 being R in position 3 and S, and the only defined positions in SEQ ID NOs: 5, 8 and 9 being S. The specification provides no guidance on how to obtain a polypeptide that is capable of being bound by a binding partner where the binding partner is not specific for phosphotyrosine, phosphoserine or phosphothreonine, as recited in claim 1. Even if the kit includes antibodies specific for an epitope other than phosphotyrosine, phosphoserine or phosphothreonine, wouldn't such antibodies also bind to the substrate polypeptides of the kit? Likewise, the specification fails to fully describe the phosphorylation-state-sensitive binding partners for this genus of polypeptides. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

7. *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). Therefore, only the polypeptides comprising SEQ ID NO: 6 (RARTLSFAEPG, KKLNRTLSFAEPG and RRRLSFAEPG recited in the legend for figure 2), but not the full breadth of the claims, meet the written description provision of 35 U.S.C. §112, first paragraph.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-3, 6, and 8 are rejected under 35 U.S.C. 102(a) as being anticipated by Albert *et al.* (Molecular Biology of the Cell, 4th ed., **2002**, pages 176-178). Alberts *et al.* teach that more than one-third of the 10,000 or so proteins in a typical mammalian cell are phosphorylated at any given time (page 177). Many of the proteins have binding partners in the cell that are sensitive to their phosphorylation state, a property fundamental to signal transduction processes. The cells contain a large collection of protein kinases. Thus, a mammalian cell as described by Alberts *et al.* comprises more than two protein kinase substrate polypeptides, each polypeptide comprising a specificity conferring portion which is different for each polypeptide and a phosphorylatable portion, as well as binding partners for the polypeptides. Although they are not called a kit by Alberts *et al.*, the cells contain the substrate peptides and binding partners and can therefore be considered a kit.

10. Claims 1-6, 8, 9, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Tan *et al.* (WO 00/14536, cited on Information Disclosure Statement). Tan *et al.* teach libraries comprising more than two protein kinase substrate polypeptides each polypeptide comprising a specificity conferring portion which is different for each polypeptide and a phosphorylatable portion. The libraries include peptides with the sequences XXXXXXT*XXXXXXC (example 1), PXS*P (example II), XXXXRSXS*XPXXXXC (example III), and PXT*/S*PXR (example IV), wherein X is any amino acid and * indicates phosphorylation. The T*, S* and T*/S* in

these sequences represent the phosphorylatable portions whereas the flanking sequence represent the specificity conferring portion. Tan *et al.* also teach antibodies that bind to these substrate peptides in a phosphorylation-dependent manner. The antibodies in example IV recognize the proline and arginines in addition to the phosphotyrosine and therefore are not simply anti-phosphotyrosine antibodies. Thus, the limitations of claims 1-4 are satisfied. With respect to claim 5, the library of example IV is conjugated to a tripeptide making it 9 amino acids in length. With respect to claim 6, the library of example IV is a substrate for a serine/threonine kinase. With respect to claims 8, 9, 24 and 25, the antibody of example IV is reacted with the peptide library. Although they are not called a kit by Tan *et al.*, the library and antibody, the substrate peptide and binding partner, are provided together.

Allowable Subject Matter

11. Claim 10 is allowable.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Marchetti Bradley whose telephone number is (571) 272-9044. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cecilia J. Tsang
Supervisory Patent Examiner
Technology Center 1600

Christina Marchetti Bradley, Ph.D.
Patent Examiner

Art Unit 1654

cmb

Notice to Comply	Application No. 10/510,875	Applicant(s) ARMSTRONG ET AL.	
	Examiner Christina Marchetti Bradley	Art Unit 1654	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e). The correct SEQ ID NO:2 is present in the paper copy of the of the sequence listing only. Therefore a search of the correct sequence is not possible.

☒ 7. Other:

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application**.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216 or (703) 308-2923
For CRF Submission Help, call (703) 308-4212 or 308-2923
PatentIn Software Program Support
Technical Assistance.....703-287-0200
To Purchase PatentIn Software.....703-306-2600

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR REPLY